ERT®
Confidence at every turn™

eCOA SOLUTIONS

Eliminate eCOA complexity so you can move ahead quickly

THE PROBLEM WITH COA

The quality of collected patient data, study timelines and study costs are influenced by a number of factors, including:

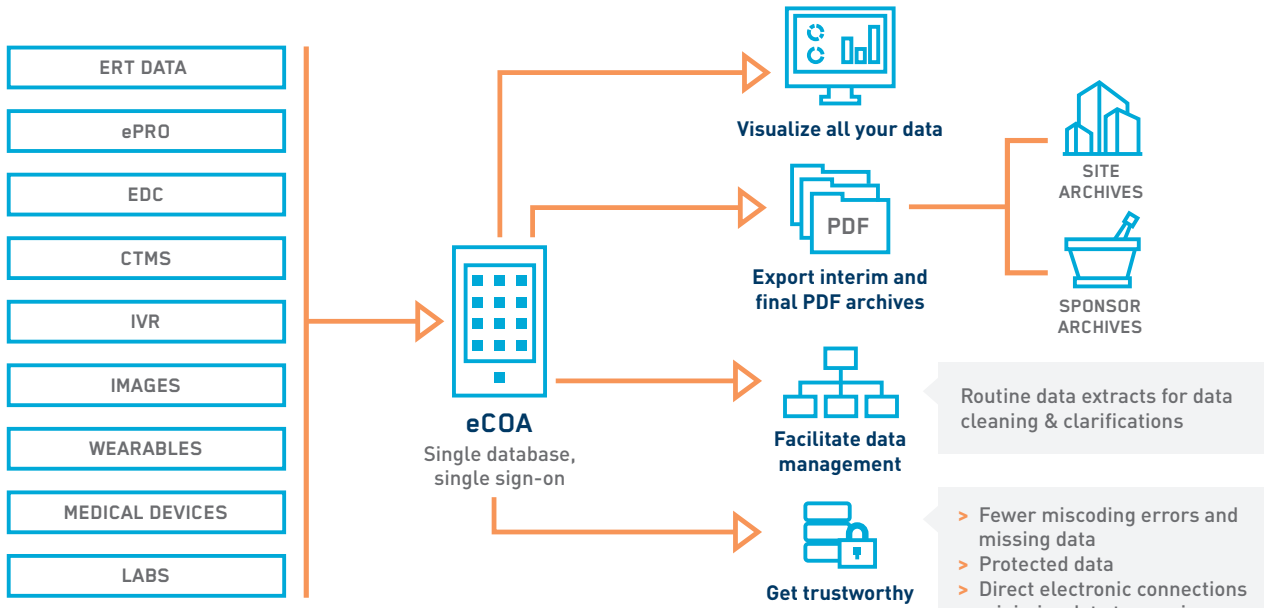
- Complex protocols
- Larger sample sizes
- Data collection in multiple languages
- Different global regulations
- Mid-study protocol changes

Paper-based data collection systems tend to be inefficient and error prone; therefore, managing these factors on paper is particularly challenging and further compromises data quality, patient safety and compound efficacy. In addition, compiling and reviewing disparate data can delay your database lock and submissions. Technological implementations are increasingly used to help manage study complexity. However, because of the multiple modalities needed to engage and retain diverse patient populations, the use of technology-based clinical outcome assessments (COA) can seem as inefficient as paper-based methods.

57% OF TRIALS UNDERGO PROTOCOL AMENDMENTS[1]

ACCELERATE YOUR RESEARCH WITH ERT eCOA

With electronic clinical outcome assessment (eCOA) technology, you can access data in real-time to view early and interim study results for regulatory review or to seek funding. But with so many solutions available, how do you know what's right for your trial? With our integrated eCOA solutions, you can accelerate your research with technology that doesn't get in the way.



ERT eCOA ENVIRONMENT: TRULY UNDERSTAND IF THE THERAPY IS BOTH EFFICACIOUS AND SAFE

Stay two steps ahead with 24/7 access to near real-time data, anticipate patient safety issues and address data quality concerns

1. Getz et al, Therapeutic Innovation & Regulatory Science 2016, Vol. 50(4) 436-441. http://dij.sagepub.com/content/50/4/436 Retrieved 4 December 2016

ELIMINATE eCOA COMPLEXITY SO YOU CAN MOVE AHEAD QUICKLY

Not all eCOA technologies are created equal. We've applied more than 20 years of scientific and technical experience collecting high-quality data for global clinical trials, providing electronic systems for more than half of all drug approvals since 2013.

Be certain about trial design and execution

Our eCOA scientists review every protocol to ensure maximum patient engagement and suitable content. Consistent design facilitates predictable data collection and more efficient study change management.

Improve data quality and increase patient engagement

You can easily collect data from diverse patient populations with our multi-modality capabilities. Collect patient data anywhere — whether collecting data on a handheld, tablet, browser or bring-your-own-device (BYOD). Universal screen features and functions facilitate consistent and predictable data collection, avoiding study bias.

Stop manually collating patient data from different sources

With our eCOA, your study database can be integrated with medical devices, EDC, labs, IVR and other streams. You only need a single sign-on account for a comprehensive view of all patient data.

Anticipate issues in near real time

No more waiting until study close to understand what's been happening in your trial. Instead, audit study performance online 24/7 using near real time operational and clinical data reporting that's centralized. Heat mapping is available for patient/site enrollment, compliance & trending, visit schedules and device inventories for at-a-glance identification of problem areas.

Streamline the submission process

Our eCOA solutions provide two archives to meet regulatory needs — a complete archive for each site and an archive with de-identified data for sponsors. Archives are in the required PDF-submissible format, and contain all data and documentation necessary to recreate any trial for health authorities.

Learn how you can accelerate your research with eCOA technology that doesn't get in the way. For more information, email sales@ert.com.

2100+ eCOA TRIALS

56 eCOA DRUG APPROVALS

120,000+ eCOA SITES

840,000+ eCOA PATIENTS

94 COUNTRIES SUPPORTED

106 LANGUAGES SUPPORTED

MINIMIZE RISK

Rater training and gating

Safeguard the standardized use of each instrument

- Interactive video and quiz training on-device or via web
- Training for patients, caregivers and clinicians
- Gating to link eCOA and rater training environments
- Fully configurable training platform adjustable to study needs

Suicide risk assessment

Electronic deployment of suicide risk assessment

- Integrate the C-SSRS and eC-SSRS, gold standard assessments for SIB
- Accelerated screening and identification of patients at risks
- Self-report enables detection of more severe events

Anticipatory oversight

Anticipate issues in near real-time with 24/7 access to data

- Centralized reporting oversight of all study data at your fingertips
- Predictive analytics based on relationships between patient data and lab and medical device data
- Alerts for patient safety

Streamlined submission process

Streamline submission process with full regulatory compliance

- Full compliance with global regulations
- Two archives to meet regulatory needs: a complete archive for each site and an archive with de-identified data for sponsors
- Archives in the required PDF-submissable format

HAVE CONFIDENCE AT EVERY TURN

Scientific expertise paired with every protocol

Our eCOA clinical scientists review every protocol

- Ensure fit-for-purpose study design
- Design practices proven to efficiently collect well-chosen endpoints
- Regulatory compliance and validated instrument design

Patient and site engagement evidence

Ensure optimal patient and site compliance

- Ongoing research to quantify patient preferences
- Best practices minimize patient burden and improve communications
- Site training via on-device and web-based workflows

Consistent, standardized eCOA

Migrate paper-based assessments, instrument development and validation

- Cognitive briefing and usability testing ensure content validity
- Assessments vetted through scientific focus groups
- Publication of repeatable, valid findings

Study database integration

Stop manually collecting and collating patient data from different sources

- Integrate study database with medical devices, EDC, labs, IVR and other streams
- Leverage universal screen features and functions for more standardized data
- Single sign-on for a comprehensive view of all patient data

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With more than 40 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement, and measure the efficacy of new clinical treatments while ensuring patient safety. Over the past three years, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotechs, and CROs have relied on ERT solutions in 9,000+ studies spanning three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.